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# 510(k) Summary of Safety and Effectiveness

**Date Prepared**

November 10, 2007

**Submitter's Information**

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**Device Name**

| | |
|---|---|
| Common/Usual Name: | Picture Archiving Communications System |
| Proprietary Name: | CMRtools and plug-ins VentricularTools & ThalassaemiaTools |
| Classification Names: | System, image processing, radiological 892.2050 90-LLZ |

**Substantially Equivalent to both:**

| 510(k) Number | K060941 | K994283 |
|---|---|---|
| **Device Classification Name** | system, image processing, radiological | system, nuclear magnetic resonance imaging |
| **Device Name** | CAAS MRV VERSION 3.0 | MRI- MAGNETIC RESONANCE ANALYTICAL SOFTWARE SYSTEM |
| **Applicant** | PIE MEDICAL IMAGING B.V.<br>7450 Flying Cloud Dr.<br>Eden Prairie, MN 55344 | MEDIS MEDICAL IMAGING SYSTEMS, B.V.<br>Poortgebouw Rijnsburgerweg 10<br>Leiden, NL 2333 AA |
| **Regulation Number** | 892.2050 | 892.1000 |
| **Classification Product Code** | LLZ | LNH |
| **Decision Date** | 04/19/2006 | 08/30/2000 |
| **Decision** | substantially equivalent (SE) | substantially equivalent (SE) |
| **Classification Advisory Committee** | Radiology | Radiology |

**Device Description**

CMRtools™ is a software package for the visualization and analysis of cardiovascular magnetic resonance images (CMR). CMRtools™ is comprised of an image loader, an image viewer and a set of optional plug-ins for specialist cardiac analysis, including VentricularTools and ThalassaemiaTools.

- VentricularTools provides dedicated functionality for calculating volume and mass indices of the ventricles of the heart from magnetic resonance images.
- ThalassaemiaTools allows the calculation of a property called T2* that characterizes iron loading in the heart and liver.

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# 510(k) Summary of Safety and Effectiveness

CMRtools™ allows high performance image manipulation, 3D visualization, and advanced image processing on a standard PC without dedicated hardware. All software plug-ins have comprehensive quantification facilities with full analysis session record for providing comprehensive audit trails.

## Indications for Use

CMRtools™ and plug-ins VentricularTools™ & ThalassaemiaTools™ is a software device used for viewing and analyzing cardiovascular magnetic resonance images. It allows high performance image manipulation, 3D visualization, and advanced image processing on a standard PC without dedicated hardware. All software plug-ins have comprehensive quantification facilities with full analysis session recording for providing comprehensive audit trails. It contains an image viewer for importing DICOM images, browsing through patient datasets, viewing cine images and performing region-of-interest analysis. Plug-ins are used for specialist cardiac assessment including VentricularTools for left ventricular assessment and ThalassaemiaTools for T2* image quantification. It is important that CMRtools is only used to view and analyze human cardiac and or liver images acquired with a cardiovascular magnetic resonance scanner. CMRtools must not be used to view or analyze images acquired with any other type of imaging device. The software must not be used to view or analyze images of any part of the body except the heart and or liver or the vascular system. Furthermore, the software must not be used to view or analyze images acquired from animals. Only DICOM images will be used for presentation, display and diagnosis.

## Technological Characteristics

CMRtools and plug-ins is a stand-alone software package which can be used on more than one hardware platform, as long as minimum hardware requirements are met. The device does not contact the patient, nor does it control any life-sustaining devices. A physician providing ample opportunity for competent human intervention interprets images and information being displayed and/or printed.

CMRtools and its plug-ins require a PC or a laptop with a mouse, keyboard and display running Microsoft Windows XP/Vista with a 1GHz processor, 512MB RAM, 128MB graphics card and 2GB of free hard disk space. The user interacts with CMRtools and its plug-ins using a desktop or laptop computer with a keyboard, mouse and display. The Software utilizes the standard point-and-click approach to user interface design that is ubiquitous on modern windowing operating systems.

CMRtools provides a user interface with individual items for selecting images, changing the brightness/contrast and accessing the different aspects of functionality. The plug-ins for CMRtools make use of a workflow orientated graphical user interface that guides the User through the analysis process by presenting a set of simple tasks. Each aspect of the software is clearly documented with context-sensitive Interactive Help. CMRtools and its plug-ins are designed to be used after the scanning of the patient is complete. The images will typically be transferred via a CD, network drive or though a PACS transfer from the scanner onto the clinician's local machine. Image viewing and analysis can then be performed without connection to the internet or a network.

## Testing

CMRtools and plug-ins have been tested according to the specifications that are documented in a Software Test Plan. Testing is an integral part Cardiovascular Imaging Solutions Ltd. software development process as described in the company's Product Development Process.

## Conclusion

The 510(k) pre-market notification for the CMRtools and plug-ins VentricularTools & ThalassaemiaTools contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate device.

1. The device has been and will continue to be manufactured according to the voluntary standards list in the Voluntary Standards section of the submission.
2. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "Minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2008

Cardiovascular Imaging Solutions Ltd.
c/o Mr. Carl Thomas, Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K073194
Trade/Device Name: CMRtools™ and plug-ins VentricularTools™ & Thalassaemia Tools™
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 12, 2007
Received: November 13, 2007

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

TAB2



(Indications for Use Form)

510(k) Number:

Device Name:
CMRtools™ and plug-ins VentricularTools™ & ThalassaemiaTools™

Indications for Use:

CMRtools™ and plug-ins VentricularTools™ & ThalassaemiaTools™ is a software device used for viewing and analyzing cardiovascular magnetic resonance images. It allows high performance image manipulation, 3D visualization, and advanced image processing on a standard PC without dedicated hardware. All software plug-ins have comprehensive quantification facilities with full analysis session recording for providing comprehensive audit trails. It contains an image viewer for importing DICOM images, browsing through patient datasets, viewing cine images and performing region-of-interest analysis.

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The software must not be used to view or analyze images of any part of the body except the heart and or liver or the vascular system. Furthermore, the software must not be used to view or analyze images acquired from animals.

Only DICOM images will be used for presentation, display and diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073194